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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,484	01/28/2002	Pnina Fishman	FISHMAN=8	5642

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EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,484	FISHMAN, PNINA	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0503*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-12 in the reply filed on September 30, 2004 is acknowledged. The traversal is on the ground(s) that search of both inventions is not a burden on the Examiner. This has been found persuasive and the restriction requirement has been withdrawn. Claims 1-16 are present for examination.

Claim Rejections - 35 USC § 112

1. Claims 9 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the LMW-A3RAg which is adenosine, does not reasonably provide enablement for a synthetic molecule having the same chemical structure of any other LMW-A3RAg obtained from muscle cells or white blood cells . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Other than adenosine, the specification fails to specifically identify any other chemical compound having a defined chemical structure. LMW-A3RAg substances are identified only either as a crude extract of conditioned media of muscle or white blood cells or as fractions of this extract. No specific compounds are identified and no chemical structures are disclosed. It even remains unclear as to the number of LMW-A3Ag's that are actually present in the conditioned media. One who would practice the claimed invention would need the chemical structure of one of the LMW-A3Ag's (other

than adenosine) in order to even try to make it synthetically. Further, not all chemical compounds that are found naturally may be made synthetically due, for example, to the inability to maintain necessary enzymes in an active state outside of a living cell. In the least, one who would practice the invention would need the guidance of the chemical composition of a molecule in order to have the reasonable expectation of being able to make it synthetically. Without this guidance, one who would practice the invention of claim 9, outside of use of adenosine, would engage in an undue amount of experimentation to just isolate a single molecule that would have the required activity, and to then determine its' chemical structure and then, the practitioner would still not have a reasonable expectation of success of producing it synthetically.

2. Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The claims, drawn to therapeutic methods of treatment, do not recite an object of the practice of the method other than therapy. As such, the metes and bounds of the desired treatments are not distinctly described or claimed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-16 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Bar-Yehuda et al.

The reference to Bar-Yehuda et al. discloses the LMW-A3Rag of the claims as well as the compositions and methods of the claims. It is noted that, while the inventive entities of the claimed invention and the reference share a common inventor, the inventive entity of the Bar-Yehuda et al. reference differs from the inventive entity of the claimed invention and therefore, the reference is deemed to be within the scope of the statute ("by others . . . before the invention thereof by applicant for a patent.").

6. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9609060 or U.S. Patent 5,962,331 to Fishman et al.

The references disclose low molecular weight factors having the same molecular weight of less than 3,000 Dalton, the same sources (conditioned medium from either muscle cell culture or white blood cell culture), the same characteristics of being water soluble, heat stable and non-proteinaceous and the same pharmacological anti-tumor activity. The references also disclose pharmaceutical compositions and methods of treatment as claimed (see, for example, cols. 3 and 4). In view of the identical nature of both multiple physical and functional characteristics, claim recitations of the property of resistance to adenosine deaminase activity, of the specific receptor binding activity (A3R), and of the pharmacological activity of inhibition of adenylate cyclase in target cells are deemed inherently present in one of the factors disclosed. With regard to claim 9, recitation of the term "synthetic molecule", in view of the claim requirement of

identical chemical structure with the naturally occurring molecule, is deemed a recitation of product-by-process. The process by which a claimed product is produced fails to confer patentability to claims to that product, when the product is identical to an old product.

7. Claims 1-6, 9-13 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Fishman et al. (Cancer Research 58:3181-3187 (July 15, 1998)).

The claims recite a synthetic naturally occurring low molecular weight adenosine A3 receptor agonist, pharmaceutical compositions containing same and a method for therapeutic treatment comprising administering an effective amount of the agonist. Fishman et al. identify adenosine as such an agonist, which is naturally occurring, has a low molecular weight and when administered to mice, has an anti-tumor effect. The structure of adenosine is well known and the chemical may be made synthetically. However, recitation of the term "synthetic molecule", in view of the claim requirement of identical chemical structure with the naturally occurring molecule, is deemed a recitation of product-by-process. The process by which a claimed product is produced fails to confer patentability to claims to that product, when the product is identical to an old product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jean C. Witz
Primary Examiner
Art Unit 1651